UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

SCHERING-PLOUGH HEALTHCARE PRODUCTS, INC.,

Plaintiff,

v. Case No. 07-CV-642

SCHWARZ PHARMA, INC., KREMERS URBAN, LLC, BRECKENRIDGE PHARMACEUTICALS, INC., and PADDOCK LABORATORIES, INC.,

Defendants.

ORDER

This case comes before the court on plaintiff Schering-Plough Healthcare Products, Inc.'s ("Schering-Plough") motion, filed pursuant to Federal Rule of Civil Procedure 59(e), which seeks relief in the form of an amendment to the judgment earlier entered by the court. Schering-Plough originally filed suit against defendants Schwarz Pharma, Inc., Kremers Urban, LLC, Breckenridge Pharmaceuticals, Inc., and Paddock Laboratories, Inc. (collectively, "the defendants"), alleging claims pursuant to Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B), and Wisconsin state law. In its suit, Schering-Plough claimed that the defendants made false and misleading statements regarding Polyethylene Glycol 3350 Powder for Oral Solution laxative drugs ("Polyethylene Glycol 3350"), a drug marketed and sold by the defendants. The defendants filed motions to dismiss, which the court granted in February 2008. Specifically, the court dismissed Count I of Schering-Plough's

complaint, false advertising under the Lanham Act, with prejudice, and dismissed Counts II-IV, the remaining state law claims, without prejudice.

The court's dismissal with prejudice of Schering-Plough's false advertising claim is the subject of the instant motion to alter or amend judgment. Schering-Plough requests amendment "only insofar as it dismisses the Lanham Act claim *with* prejudice." (emphasis in original) (Pl.'s Mot. Alter J., p. 1). For the reasons discussed below, the court will grant Schering-Plough's motion to alter or amend the judgment to reflect dismissal of the Lanham Act claim without prejudice.

BACKGROUND

Schering-Plough markets an over-the-counter Polyethylene Glycol 3350 product called MiraLAX. Schering-Plough received the exclusive right to market over-the-counter Polyethylene Glycol 3350 from Braintree Laboratories, Inc. ("Braintree"). Prior to granting this right to Schering-Plough, Braintree submitted a New Drug Application ("NDA") to the United States Food and Drug Administration ("FDA") to market Polyethylene Glycol 3350. The FDA initially granted approval for Braintree to market Polyethylene Glycol 3350 as a prescription-only drug in 1999. In 2006, the FDA granted approval for Braintree to market Polyethylene Glycol 3350 as an over-the-counter drug. Braintree received three-year exclusivity to market Polyethylene Glycol 3350 over-the-counter; an exclusive right which Braintree then granted to Schering-Plough.

The FDA granted approval of Polyethylene Glycol 3350 pursuant to a comprehensive drug approval and regulatory scheme under the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301-399. Under the statute, new drugs must be approved by the FDA before they can be sold. This approval may be obtained in one of two ways: 1) through a New Drug Application (NDA); or 2) through an Abbreviated New Drug Application (ANDA). A "generic" product similar to an NDA-approved "pioneer" drug may be approved and marketed based on an ANDA. *See* 21 U.S.C. § 355(j). An ANDA requires the manufacturer of the similar "generic" drug to demonstrate that the two drugs are therapeutically equivalent, that is, pharmaceutically equivalent and bioequivalent. *Id.* at § 355(j)(2)(A)(i)-(viii). More importantly for purposes of the plaintiff's suit, an ANDA also requires the "generic" drug to have the same label as the one approved for the "pioneer" drug. *Id.* at § 355(j)(2)(A)(v).

Defendants are all companies that market and sell "generic" Polyethylene Glycol 3350 products based on FDA-approved ANDA's. However, the time line of the FDA's approval of the ANDA's is relevant to the instant motion. Defendants filed ANDA's with the agency after the FDA's approval for Braintree to market Polyethylene Glycol 3350 as a prescription-only drug, but prior to the FDA's approval for Braintree to market the drug over-the-counter. The FDA approved the ANDA's, permitting the defendants to market Polyethylene Glycol 3350 as a prescription-only drug. The defendants proceeded to market and sell their Polyethylene Glycol 3350

products as "Rx only" or "prescription only" laxatives. The defendants' use of such labeling gave rise to Schering-Plough's claims of false advertising in violation of the Lanham Act. Schering-Plough asserted in its action that the "prescription only" statements on defendants' labels were false because Polyethylene Glycol 3350 is available from Schering-Plough as an over-the-counter product.

In response to Schering-Plough's claims, the defendants filed motions to dismiss arguing that the "prescription only" labels are required by the FDA and the FDCA. The defendants reasoned that because their ANDA's were based upon the earlier-approved NDA, which allowed marketing of Polyethylene Glycol 3350 as a prescription-only drug, the products' labels must indicate "prescription only." Employing this argument, the defendants each filed a motion to dismiss for failure to state a claim. Schering-Plough also filed its own dispositive motion; a motion for partial summary judgment as to liability on Count I of its complaint. By an order dated February 29, 2008, this court granted the defendants' motions to dismiss and denied Schering-Plough's motion for partial summary judgment. Schering-Plough now requests a limited amendment of the judgment.

ANALYSIS

A party may move the court to alter or amend its judgment under Federal Rule of Civil Procedure 59(e). However, the petitioner must demonstrate either a manifest error of law or present newly discovered evidence. *Obriecht v. Raemisch*, 517 F.3d 489, 494 (7th Cir. 2008) (citing *Sigsworth v. City of Aurora*, 487 F.3d 506,

511-12 (7th Cir. 2007)). The decision whether to grant a Rule 59(e) motion to alter or amend "is entrusted to the sound judgment of the district court." *In re Prince*, 85 F.3d 314, 324 (7th Cir. 1996) (citing *LB Credit Corp. v. Resolution Trust Corp*., 49 F.3d 1263, 1267 (7th Cir. 1995)).

Schering-Plough moves this court to amend its judgment to dismiss Schering-Plough's Lanham Act claim *without* prejudice, rather than dismissing the claim *with* prejudice. Schering-Plough argues that the court did not decide the claim on its merits but, rather, determined that the plaintiff's claim was premature, or "unripe." Schering-Plough asserts that the appropriate method for addressing unripe claims is dismissal without prejudice. Therefore, the court's dismissal with prejudice constitutes a "manifest error of law" and the court should amend its judgment to dismissal without prejudice. Such an amendment, Schering-Plough argues, would permit it to re-file the Lanham Act claim if and when the FDA determines that the defendants' products are misbranded.

In response, the defendants argue that the court *did* decide Schering-Plough's claim on the merits. Therefore, the court properly dismissed the claim with prejudice. To support their argument, defendants assert that the FDA approved and required the labeling that appears on their products. Thus, no private right of action exists under the Lanham Act and challenges to defendants' labeling can only be addressed by the agency. Finally, the defendants argue that a dismissal for failure

to state a claim does constitute an adjudication on the merits because Rule 41(b)[1] applies to Rule 12(b)(6) dismissals.

The dispute between Schering-Plough and the defendants is primarily one of interpretation. Under the arguments posited by the parties, the court's decision dismissing Schering-Plough's Lanham Act claim is either: a) a decision on the merits appropriately dismissed with prejudice; or b) a decision that the claim is unripe, which warrants only dismissal without prejudice. The court's resolution of the issue is dispositive of whether the court should appropriately amend its judgment.

Therefore, the court clarifies that its dismissal of Schering-Plough's Lanham Act claim was not an adjudication on the merits. Instead, the court deemed Schering-Plough's claim to be premature because the FDA had not yet addressed whether the defendants' "prescription only" drugs were misbranded based on the agency's approval for over-the-counter sales of the same drug. This court quotes its own language as evidence that it deemed Schering-Plough's claims unripe. The court expressly declined to reach the merits of the claim, stating that "a ruling on the merits...would require the court to usurp the FDA's responsibility for interpreting and enforcing the agency's regulations." (Order, p. 13). The court further stated, "..the FDA has not yet taken any official position concerning the labeling of the defendants'

[1]Federal Rule of Civil Procedure 41(b) states: "...Unless the dismissal order states otherwise, a dismissal under this subdivision (b) and any dismissal not under this rule...operates as an adjudication on the merits."

products to which the court can defer." *Id.* Finally, the order notes that the court cannot properly decide the claim before the agency receives an opportunity to do so:

> Accordingly, because the FDA *has not yet made a final determination* regarding these marketing and labeling issues, and because Schering-Plough's Lanham Act claim would require this court to "determine preemptively how a federal agency will interpret and enforce its own regulations," the court is obliged to dismiss Schering-Plough's Lanham Act claim.

(emphasis added) (Order, p. 16). These statements are wholly unnecessary if the court can never hear a Lanham Act claim on the issue, as the defendants assert. If the court can never hear such a claim under any circumstances, it would simply state this conclusion instead of referencing an agency position "to which the court can defer," or the fact that the FDA "has not yet made a final determination."

In addition, the defendants' assertion assumes that half of the court's order is superfluous. The court spent nine pages of its order analyzing whether the defendants' labels constitute literally false statements under the Lanham Act before denying Schering-Plough's motion for partial summary judgment. These pages are a waste of ink if the court, in its very next paragraph, held that a court may never consider a Lanham Act claim like the one brought by Schering-Plough. Instead, an FDA resolution of its seemingly contradictory approval of both the defendants' "prescription only" labels and the plaintiff's over-the-counter sales of the same drug would eliminate the danger of impermissible court interference in the agency's interpretation and enforcement of its regulations.

Finally, the court need not address the merits of Schering-Plough's claim prior to determining that a dismissal should be "without prejudice." Defendants assert that the court necessarily decided Schering-Plough's claim on the merits because a viable Lanham Act claim cannot possibly arise. The defendants argue that, even if the FDA makes a determination regarding the misbranding of their products, Schering-Plough cannot sustain a claim under either possible scenario. The defendant argues the two scenarios as follows: 1) if the FDA declines to withdraw approval of the generic drugs, then the defendants' products are not misbranded and no claim can arise; or 2) if the FDA withdraws approval for the drug labels, the withdrawal will not apply retroactively to create a claim for false representation and the defendants would immediately stop marketing the drugs, precluding any claim by the plaintiff. However, the court need not evaluate the merit of a future suit before allowing Schering-Plough the opportunity to bring such a suit by dismissing the claim without prejudice. *See Country Mut. Ins. Co. v. American Farm Bureau Federation*, 876 F.2d 599, 601 (7th Cir. 1989) ("Because we agree with the district court that the [Lanham Act claim] is unripe, we need not pursue the subject, but it will come to the fore should the litigation resume.")

The court held that it could not decide Schering-Plough's claim before an FDA determination that defendants' drugs were misbranded. Thus, the decision constitutes a dismissal because the claim was unripe, not because the court can never hear such a claim or because the claim is inherently meritless. Therefore, the

court will grant a limited amendment of the judgment to dismiss Count I of Schering-Plough's complaint without prejudice.

Accordingly,

IT IS ORDERED that Schering-Plough's motion to alter judgment (Docket #98) be and the same is hereby **GRANTED**; Count I of the complaint is hereby **DISMISSED without prejudice**.

Dated at Milwaukee, Wisconsin, this 22nd day of January, 2009.

BY THE COURT:

J.P. Stadtmueller
U.S. District Judge